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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/069,228	02/21/2002	Shuji Hinuma	46342/57113	1875

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EXAMINER	
LOCKARD, JON MCCLELLAND	
ART UNIT	**PAPER NUMBER**
1647	

DATE MAILED: 01/27/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/069,228	HINUMA ET AL.	
	Examiner	Art Unit	
	Jon M Lockard	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 October 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-3* is/are pending in the application.

4a) Of the above claim(s) *2* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1 and 3* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-3* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *21 February 2002* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☒ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *2/21/02*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of Group I, claims 1 and 3 drawn to methods of screening ligands or compounds that promote or inhibit a function of an orphan receptor protein, in the reply filed on 07 October 2004 is acknowledged. Applicants traverse on the grounds that the product claimed in Group II cannot be made by a process which is materially different from that set forth in the restricted claims. This is not found persuasive because neither claim 1 or 3 comprise a biosynthetic process. Therefore the claimed product of Group II is a compound identified by the methods of Group I (claims 1 and 3), not a compound that is made by the methods.

2. The restriction requirement is still deemed proper and is therefore made FINAL.

3. Claim 2 is withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 07 October 2004.

Status of Application, Amendments, And/Or Claims

4. Applicants' amendment filed on 07 October 2004 has been received and entered in full. Claims 1 and 3 are under consideration.

Priority

5. Acknowledgment is made of applicant's claim for foreign priority based on an application filed in Japan on 24 August 1999. It is noted, however, that applicant has not filed a certified copy of the 236597/1999 application as required by 35 U.S.C. 119(b).

Information Disclosure Statement

6. The Information Disclosure Statement (IDS) submitted on 21 February 2002 has been considered by the Examiner. References BB, BC, and BD have been considered to the extent of the abstract only, as the remainder of the references are not in the English language.

Drawings

7. The drawings are objected to because the figure in the instant application does not comply with 37 C.F.R. 1.84(U)(1), which states that "[w]here only a single view is used in an application to illustrate the claimed invention, it must not be numbered and the abbreviation "FIG" must not appear".

8. A corrected drawing sheet in compliance with 37 CFR 1.121(d) is required in reply to the Office action to avoid abandonment of the application. The figure or figure number of an amended drawing should not be labeled as "amended." If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Specification

9. The abstract of the disclosure is objected to because it is too long and more than one paragraph in length. Correction is required. See MPEP § 608.01(b).

10. Applicant is reminded of the proper language and format for an abstract of the disclosure. The abstract should be in narrative form and generally limited to a single paragraph on a separate sheet within the range of 50 to 150 words. It is important that the abstract not exceed 150 words in length since the space provided for the abstract on the computer tape used by the printer is limited. The form and legal phraseology often used in patent claims, such as "means" and "said," should be avoided. The abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details. The language should be clear and concise and should not repeat information given in the title. It should avoid using phrases which can be implied, such as, "The disclosure concerns," "The disclosure defined by this invention," "The disclosure describes," etc.

11. The Claims should be the object of a sentence starting with "(I or We) claim", "The invention claimed is," or the equivalent. See M.P.E.P. 608.01(m).

Claim Rejections - 35 USC § 112, 2nd paragraph

12. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

13. Claims 1 and 3 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

14. Claims 1 and 3 are indefinite for reciting the phrase "capable of expressing". Does this refer to a cell that actually expresses the receptor (naturally or as a result of genetic manipulation) all of the time, part of the time, or only in the proper conditions, or does it refer to any cell that could potentially express the receptor protein if were transfected with the appropriate cDNA.

15. Claims 1 and 3 are further indefinite because the metes and bounds of the limitation "a common structure" cannot be clearly determined. It is unclear how much the structure of the candidate compound can deviate from a referenced structure and still have "a common structure".

16. Claims 1 and 3 are further rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. Part (iii) of each claim, "by considering a common structure", does not set forth any steps involved in the method/process, therefore it is unclear what method/process is encompassed by the claim.

17. Claims 1 and 3 are further rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. Part (iiii) of each claim, measuring amount of specific binding between said orphan receptor protein and test compound, does not set forth any steps involved in the method/process, therefore it is unclear what method/process is encompassed by the claim. Furthermore, the same holds true for parts (b), (c), (d), (e), and (f) of the claim.

18. Claims 1 and 3 are further indefinite for reciting the phrase "measuring a cell stimulating activity to be measured" in parts (i) and (iii) of claim 1 and part (i) of claim 3. It is unclear how

one would compare an activity that has not been measured yet, i.e, "to be measured".

19. Claim 1 is further indefinite because the two parts of claim 1, part (iii), do not relate to each other.

20. Claim 1 is further indefinite because part (iii) of the claim does not clearly relate back to the preamble. It is not clear how measuring the amount of specific binding in part (iii) of the claim identifies a compound that promotes or inhibits a function of an orphan receptor protein.

Claim Rejections - 35 USC § 102

21. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

22. Claims 1 and 3 are rejected under 35 U.S.C. 102(b) as being anticipated by Aiyar et al. (A cDNA encoding the calcitonin gene-related peptide type 1 receptor. The Journal of Biological Chemistry. 271(19):11325-11329. 1996.). Aiyar et al. teach a screening method to identify a test compound (CGRP) which binds to membrane fractions obtained from cells transformed with an orphan receptor as well as membrane fractions of untransfected cells as a control (See Experimental Procedures: Binding Assays, page 11326; Figure 3, page 11327). Aiyar et al also teach a functional assay method to identify a test compound that stimulates activity in cells that are transformed with an orphan receptor as well as untransfected cells as a control via measuring cyclic AMP (See Experimental Procedures: Functional Assays, page

11326; Figure 4, page 11328). In both screening methods, Aiyar et al. additionally teach the screening of molecules that are analogs of CGRP (See Figures 3 and 4). Thus, Aiyar et al. teach all the limitations of claims 1 and 3.

23. Claims 1 and 3 are rejected under 35 U.S.C. 102(b) as being anticipated by Zhou et al. (Molecular cloning and characterization of an adenosine receptor: the A3 adenosine receptor. Proc. Natl. Acad. Sci. USA. 89:7432-7436. 1992.). Zhou et al. teach a screening method to identify a test compound which binds to membrane fractions obtained from cells transformed with an orphan receptor as well as membrane fractions of untransfected cells as a control (See Results, page 7433¶3; Figure 3, page 7435). Aiyar et al also teach a functional assay method to identify a test compound that stimulates activity in cells that are transformed with an orphan receptor as well as untransfected cells as a control via measuring cyclic AMP (See Results, page 7433-7435; Figure 4A, page 7435). In both screening methods, Zhou et al. additionally teach the screening of molecules that are analogous compounds (See Figures 3 and 4, page 7435). Thus, Zhou et al. teach all the limitations of claims 1 and 3.

Summary

24. No claim is allowed.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Jon M. Lockard, Ph.D.** whose telephone number is **(571) 272-2717**. The examiner can normally be reached on Monday through Friday, 8:00 AM to 6:00 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, **Brenda Brumback, Ph.D.** can be reached on **(571) 272-0961**.

The fax number for the organization where this application or proceeding is assigned is **703-872-9306**.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see **http://pair-direct.uspto.gov**. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at **866-217-9197** (toll-free).

JML
January 17, 2005

LORRAINE SPECTOR
PRIMARY EXAMINER